MDMA MEDICAL DEVICE MANUFACTURERS ASSOCIATION

July 23, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Subject: FDA Docket No. 99D-0239 – Draft Guidance on "**Resolving Scientific Disputes Concerning the Regulation of Medical Devices**"

Dear Sir or Madam:

The Medical Device Manufacturers Association (MDMA) appreciates this opportunity to comment upon the above-referenced draft guidance document published April 27 by the FDA's Center for Devices and Radiological Health (CDRH).

MDMA, based in Washington, D.C., is the national association for the innovators and entrepreneurs in the medical device industry. Representing 130 independent manufacturers of medical devices, diagnostic products, and health care information systems, MDMA seeks to improve the quality of patient care by encouraging the development of new medical technology and fostering the availability of beneficial innovative products in the marketplace.

Section 562 of the Federal Food, Drug, and Cosmetic Act mandates that the FDA "shall, by regulation, establish a procedure under which [a sponsor] may request a review" of a "scientific controversy" between the agency and the sponsor of a product. However, the agency has instead chosen to carry out its obligation through the publication of a draft guidance document, when notice-and-comment rulemaking is clearly expected under the terms of the statute.

MDMA requests that the FDA withdraw this draft guidance document and promulgate a regulation to carry out the agency's statutory obligation to develop an independent and responsive panel for the resolution of scientific disputes. By conducting this statutory requirement through a guidance document, the FDA violates the Administrative Procedures Act (APA), 5 U.S.C. §706, not to mention the clear language of the statute.

In addition, as the FDA develops its notice-and-comment rulemaking, MDMA requests that the agency consider the following points:

- The purview of the dispute resolution panel should not be limited to review of formal agency decisions or actions. Sponsors should have the right to petition this panel for

resolution of disputes that arise early in the product clearance or approval process over such issues as the reasonableness of data requirements.

- The agency should look for ways to speed the timeline of a review by the dispute resolution panel. A several-month wait between a sponsor's request for a review and a final decision will dissuade many companies from using what was intended by Congress to be a responsive and timely process.

- The final recommendation of the dispute resolution panel should stand unless the decision contradicts the law or would pose a significant threat to the public health. Providing the CDRH Director with the authority to overturn the panel's recommendation compromises the independence of the process.

Thank you for the opportunity to comment on this draft guidance document.

Very sincerely yours,

Stephen J. Northrup
Executive Director

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